

Smoking Cessation

This study will be divided into two separate phases. During the first phase, EEG recordings, behavioral measurements and respiratory gas exchanges will be done on fifty habitual smokers (one pack to one and one half packs a day). The subjects will be told exactly what the study is about, namely to obtain information on the habitual state of a smoker. A widely used questionnaire relative to state of anxiety, the "MALL", will be filled out by the subjects (see enclosed instructions and disclosures before obtaining consent). A simple questionnaire on smoking habits will also be filled out (copy enclosed).

In the second phase, the subjects will be recalled and offered treatment to discontinue for two to three weeks their habit. The ones interested will be briefed on the procedures to be used. They will be recorded twice before treatment and twice after cessation of smoking. Although the measurement procedures to be used will be the same as used during the first phase, they will nonetheless be repeated carefully and completely. A separate consent form will be obtained.

The reason for the two distinct phases is that changes in the level of anxiety can only be detected in relation to "normal" daily routines. It is likely that the baseline measurements obtained one week or so before cessation of smoking, when the subjects know that they will have to go through the procedures, will give a somewhat distorted baseline to which to compare post-smoking cessation data.

It should be pointed out that no pressure will be applied to convince smokers to undertake cessation procedures.

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Disclosures to Subjects

Phase I

You are going to be involved in a study of certain physiological parameters in smokers. There is no hidden purpose to this study other than to obtain information on the base state of the smoker, as compared to that of the non-smoker. This is made clear by the questionnaire on smoking habits.

We are going to measure four things on you: Your EEG (brain waves), your reaction time, your respiratory exchanges insofar as gases are concerned, and finally your mood through a simple paper and pencil questionnaire. Let me explain briefly what these procedures are, what data they provide and what risks (in fact there are none) to your health and well being.

a) EEG Recordings. As you may know, the brain produces continuously varying electrical potentials which can be picked up and recorded on paper, yielding patterns of the variations of potentials in time. The EEG procedure is harmless and produces little or no discomfort. The electrodes (i.e., the units which pick up the electrical activity) are small gold-plated cups. These are put in contact with the scalp via a paste containing electrolytes. It is not exaggerated to say that the EEG has been recorded on millions of people and not a single adverse reaction has been reported. The paste is neutral and will not produce any skin reaction, even in poly-allergic subjects. Keep in mind two important things. First, the EEG machine is strictly a one-way machine insofar as electrical currents are concerned. It accepts an input but has no other output than to the recording oscillographs and their attached ink-pens. The electrode wires are one-way conductors. The EEG works like the electrocardiogram. Second, EEG patterns cannot tell anything covering your thoughts. All they tell us is the relative functional state of your brain at the time the recording is performed. The EEG is like the envelope containing a letter. By looking at the envelope we can say from where it was mailed, to whom it is addressed and how long it travelled; by the weight we can infer how much writing it contains. But that is all. We cannot say what is in the letter. So, do not worry that we will know what is on your mind. You can think of EEG recordings as wire-taping of the brain. We are, in effect, listening to what is going on in your brain. However, we do not listen to one conversation going on between two persons but an astronomical number of conversations between an astronomical number of persons going on at the same time. What we hear is something like the noise which would be generated by the population of New York City crowded into Shea Stadium with everybody talking. Since we have no way of

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unscrambling these conversations, we cannot conceivably understand their contents even in the remotest way. What we can establish, however, is knowledge on the magnitude of the participants, the speed at which they talk, the loudness of their voices, and how concordant or discordant is their conglomerated vocalization. But this is all we can get at present and probably for a long time to come. What we try to find out is whether the amount of conversation going on is the same in smokers and in non-smokers.

As soon as the recording is over (10-15 minutes), we will remove the electrodes and we promise to do a good job, so that no traces of the paste will remain.

b) Reaction Time. This is a simple procedure which permits us to measure how attentive to a task you are, and how fast you get tired. You will sit in front of a panel on which two lights will appear, either a red light or a green light. On the arm rests of the chairs are two levers. All we ask you to do is to press on the left arm lever when you see the red light and on the right arm lever when you see the green light. The signals will appear in a random fashion so you cannot forecast when the red has appeared whether the next presentation will be red or green, neither can you guess how regular or irregular the presentations will be. Try to press as quickly as you can.

c) Respiratory Gases. You will be asked to blow into a tube, so that we can determine the level of carbon monoxide in your breath. This information is needed to establish how smoking affects your respiratory exchanges. It has nothing to do with pathology.

d) Questionnaire. This is part of the inquiry into your personality. As you can see the questions are not meant to yield the kind of information which could be used against you. However, you can rest assured that all you say will be treated in strict, absolute confidentiality.

In a general way, we intend to respect your personality in the most careful way. For us, you will be a number of a certain age, weight and height. That is all. Your name will not be disclosed unless you specifically request it. We have a safe for storing information; the safe is located in a room with a lock which can only be opened by Dr. Goldstein and Security Officers.

Finally, you are free to discontinue your participation at anytime.

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Disclosures to Subjects

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understanding of the conversations, we cannot conceivably understand their contents even in the remotest way. What we can establish, however, is the degree of the Phase II of treatment. The speed at which you quit, the amount of stress you feel, the concordance or discordance in their observations, and your overall well-being. Since you are interested in discontinuing your smoking habits, we are inviting you to participate in the same studies of physiological parameters as you did previously but this time in connection with the procedures which should help you "kick the habit".

As soon as the recording is over (10-15 minutes), we will remove the electrodes. Read Disclosures for Phase I starting with the second paragraph.

Insofar as procedures for discontinuation they are as follows:

You will simply stop smoking. One of the most widely used method for counteracting the absence of cigarettes is to chew gum or to suck candies. Some people find comfort in keeping a toothpick in their mouth. You are free to use any means you want to help you go through the period without cigarettes. Do not use so-called "replacement" products such as Nicoban.

You should not be unduly worried about the effects of withdrawal from tobacco. You may become irritable or unduly nervous. However, as evidenced by a large amount of data, you should not be made really ill; uncomfortable, yes; ill, no. Again, if you cannot stand it, the solution is simple: resume smoking. Go slowly at it, that is all. If you should feel sleepy, use coffee--moderately, of course.

We intend to obtain two sets of measurements before you undergo the treatment, and one and two weeks following smoking cessation.

Again, you can discontinue your participation at any time. If you complete the procedure, you will receive a \$50.00 fee. If you dropout, you will be rewarded at the rate of \$5.00 per session attended.

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Smoking Cessation Questionnaire

Code # _____ Date _____

Age _____ Sex _____ Height _____ Weight _____

Right _____ or left _____ handed.

How long have you been smoking? _____

How did you start? _____

Have you ever tried to stop? _____ Yes _____ No.

If yes, how many times? _____ How long? _____

How many cigarettes do you use per day (average)? _____

What brand? _____

When do you smoke the first cigarette of the day? _____

When do you smoke the last cigarette of the day? _____

How long before this recording did you last smoke? _____

Did you experience any unusual event today? _____ Yes _____ No

If yes, explain _____

Did you experience any unusual event yesterday? _____ Yes _____ No

If yes, explain _____

How would you judge today insofar as your performance is concerned?

above average _____ average _____ below average _____

Do you use alcoholic beverages? _____ Yes _____ No

If yes, could you indicate (roughly) your weekly consumption:

_____ beer _____ wine _____ whiskey _____ liquor _____ other

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Smoking Cessation Questionnaire

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Age

Sex

Height

Weight

As best you can remember, list the main illnesses up until now.

at:

Any surgical operations? ☐ Yes ☐ No. If yes, which?

When

How did you sleep last night? ☐ as usual ☐ better ☐ worse

Characterize in any way you want, what effect or effects you obtain from smoking.

Are you taking any medication either on prescription or over-the-counter, such as anti-histamines or aspirin? ☐ Yes ☐ No

If yes, which

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